

REMARKS

The Office Action mailed September 28, 2007 (hereinafter, "Office Action"), has been reviewed and the Examiner's comments considered. Claims 1-32 are pending in this application. Claims 19 and 28 are amended herein. Applicant submits that no new matter or issues have been introduced.

Claim Objections

Claim 28 stands objected to due to the alleged informality of "a stent" being recited in the claim body following the recitation of "a stent" in the preamble. After reviewing the pending claims, Applicant discovered a similar "informality" in claim 19. Without conceding the propriety of the objection, Applicant has amended claims 19 and 28 in the interest of compact prosecution. Accordingly, Applicant respectfully requests withdrawal of the objection.

Double Patenting

Claims 1-32 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting (ODP) over claims 9-29 of co-pending U.S. Patent Application No. 10/572,191, having a U.S. filing date of March 15, 2006 and a foreign priority date of September 25, 2003. The instant application has a U.S. filing date of November 18, 2005 and a foreign priority date of April 28, 2003. Thus, without conceding the propriety of the ODP rejection, Applicant notes that pursuant to MPEP § 804 I.B.1, the instant application should be passed to issue without requiring a terminal disclaimer if the ODP rejection is the only rejection remaining in the instant (i.e., the earlier-filed) application.

Claim Rejections – 35 U.S.C. § 103

Claims 1-2 and 19-20 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over US 2002/0038143 to McCrea et al. (hereinafter, "McCrea") in view of USPN 5,619,878 to Grosjean et al. (hereinafter, "Grosjean"). Claims 3-18 and 21-32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over USPN 7,011,675 to Hemerick et al. (hereinafter, "Hemerick") in view of USPN 4,576,534 to Barth et al. (hereinafter, "Barth"). Claims 4-6 stand rejected under 35 U.S.C.

§ 103(a) as being unpatentable over Hemerick in view of Barth as applied to claim 3 and further in view of McCrea. Claims 11-12, 18 and 25 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hemerick in view of Barth as applied to claim 10 and further in view of USPN 6,613,075 to Healy et al. (hereinafter, “Healy”).¹ Claims 8, 17 and 22 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hemerick in view of Barth as applied to claims 3 and 10 and further in view of USPN 6,143,014 to Dehdashtian et al. Claim 31 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Hemerick in view of Barth as applied to claim 28 and further in view of USPN 6,585,753 to Eder et al. Applicant respectfully traverses these rejections.

McCrea in view of Grosjean

Independent claims 1 and 19 are directed to a method of loading a self-expanding stent into a delivery sheath. Each claim includes the step of providing a stent pusher with protrusions, compressing the stent over the protrusions to a specified configuration with respect to the protrusions and the stent, and inserting the stent pusher and stent into a delivery sheath.

The Office Action admits that McCrea does not disclose a stent pusher with protrusions, does not disclose helically arranged protrusions, does not disclose that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope, and does not disclose the step of advancing the stent into the sheath (*see* Office Action, pp. 3-4). The Office Action alleges that Grosjean “discloses that it is old and well known in the art to provide helically arranged protrusions about the surface of a pusher/mandrel in order to ease removal of the pusher/mandrel by allowing it to be unscrewed” (Office Action, p. 4). However, as to the other features of claims 1 and 19 admittedly not shown by McCrea, the Office Action asserts that it would have been obvious to modify McCrea in a manner fitting the claimed invention without any further support.

¹ Applicant notes that the rejection on p. 10 of the Office Action appears to have errors in view of the supporting discussion on p. 11. Thus, for purposes of this response, Applicant assumes the Office Action intended to include claim 25 in the rejection of claims 11-12 and 18, and also that this rejection was further in view of Healy rather than McCrea.

Without conceding that Grosjean is analogous art pursuant to MPEP 2141.01(a), Applicant respectfully submits that a method of manufacturing *corrugated* pipes by deforming a pipe over a mandrel with grooves is distinct from the claimed step of providing a stent pusher including *protrusions*. More specifically, assuming *arguendo* that the corrugated pipe of Grosjean can be fairly characterized as a stent pusher (Applicant respectfully submits that it can not be), the resulting grooved section of the corrugated pipe does not provide protrusions to “deform the covering” when a stent is compressed thereover because the pipe grooves are *within* the outer diameter of the pipe and therefore nothing *protrudes from* the outer diameter of the pipe to deform the covering (*see, e.g.*, FIGS. 1 and 3 of Grosjean compared to FIGS. 1-3 of the instant application).

Accordingly, Applicant submits that a *prima facie* case of obviousness is not established by the Office Action at least because the asserted combination does not teach or suggest all of the limitations of either claim 1 or claim 19. Therefore, Applicant submits that claims 1 and 19 are patentable over the asserted combination of McCrea and Grosjean and requests favorable reconsideration and withdrawal of the rejection of claims 1-2 and 19-20 under 35 U.S.C. § 103.

With respect to the assertion by the Office Action that “it would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the method of McCrea...” (Office Action, p. 4), it appears that an official notice has been taken by Examiner. However, as outlined in MPEP § 2144.03, official notice must be supported by evidence, which is missing from the Office Action. The claimed steps alleged by the Office Action to be obvious appear to be hindsight analysis with the benefit of the Applicant’s own disclosure. Therefore, in the event that the Examiner has taken official notice, Applicant respectfully requests the required evidence be included in the next action.

Hemerick in view of Barth

Independent claims 3 and 10 are directed to a delivery system, and independent claim 28 is directed to a method of deploying a stent. Claim 3 recites a pusher with radially outwardly extending protrusions, and claims 10 and 28 recite an inner catheter including radially outwardly extending protrusions. Also, claim 3 recites a covered stent with a covering material bonded to the

matrix lying radially inside the luminal envelope, and claims 10 and 28 recite a covering layer or covering positioned on a luminal wall surface of the stent.

The Office Action alleges that Hemerick discloses a pusher 104b (identified by Hemerick as a tube (col. 7:51-52)), but admits that Hemerick does not disclose either a pusher having radially outwardly extending protrusions or a stent positioned over the protrusions such that the protrusions deform the covering material but do not reach radially outwardly as far as the luminal envelope. The Office Action substitutes these missing features by noting first that Hemerick discloses a thickened portion 104c (identified by Hemerick as a holding sleeve (col. 8:23-26)) that frictionally engages the stent, and then that Barth discloses that “it is well known in the art to provide radially outwardly helical protrusions on a surface to increase that surface’s ability to frictionally engage a second surface” (Office Action, p. 5). The Office Action next alleges that it would have been obvious to “modify the apparatus of Hemerick by providing radially outwardly helical protrusions on the pusher 104b, specifically on the thickened portion 104c for purposes such as increasing the frictional engagement between the pusher and the stent during deployment *as taught by Barth*” (Office Action, pp. 5-6, emphasis added). Finally, the Office Action alleges that the Barth protrusions “would deform the covering material but would not reach radially outwardly as far as the luminal envelope” (Office Action, p. 6).

Initially, Applicant respectfully submits that Barth is nonanalogous art and is therefore unsuitable for a rejection of the pending claims under 35 U.S.C. § 103. According to the two-part test employed by the Federal Circuit (*see, e.g., In re Oetiker*, 24 USPQ2d 1443 (Fed. Cir. 1992), *In re ICON Health and Fitness Inc.*, 83 USPQ2d 1746 (Fed. Cir. 2007), etc.), in order to be an analogous reference, the reference must either be in the field of the applicant’s endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. Barth is directed to a screw for use with materials such as plastic, cast aluminum and other soft metals, whereas the claimed invention is directed to stent delivery systems and deployment of stents in a body. Thus, Barth is unquestionably outside of the field of Applicant’s endeavor. Moreover, the problem with which the inventor is concerned, as discussed in the instant specification, is to “load self-expanding covered stents into catheter delivery systems” with “better management of

stress within the stent tube” as the stent-graft is restrained “from proximal movement during proximal withdrawal of the delivery sheath during placement of the stent at the stenting site” (Instant Specification, p. 4). Quite differently, the Barth screw addresses problems of sufficient strip torque without increases in radial stress or drive torque and with a “larger shank diameter for a given crest diameter” (*see* Barth, col. 1:38-47). This is accomplished by “providing a screw with a thread which has an upper flank with a compound surface” (col. 1:49-50) and varying thread heights (*see, e.g.*, FIG. 5). Differently from the particular problem with which the Applicant was concerned, namely *homogenous* distribution of stress along the length and area of the stent to facilitate loading and delivery, the Barth screw is designed to distribute *radial* stress to prevent a boss from breaking during insertion as the screw deforms the boss material and thereby *increases* frictional engagement. Thus, Barth is not reasonably pertinent to the particular problem with which the Applicant was concerned.

Accordingly, Applicant respectfully submits that Barth is nonanalogous art because it is not in the field of Applicant’s endeavor and is not reasonably pertinent to the particular problem with which the Applicant was concerned. Therefore, Applicant requests reconsideration and withdrawal of the rejections using Barth as a secondary reference.

However, even assuming *arguendo* that Barth can be considered an analogous reference for purposes of a rejection under 35 U.S.C. § 103, the combination with Hemerick does not teach or suggest all of the limitations of the rejected claims. For instance, Hemerick does not show or describe a covering for the stent which is deformed by the protrusions or into which the protrusions extend, as recited in independent claims 3, 10 and 28. Instead, Hemerick describes bare stent ends that are held by friction by the holding sleeve 104c (col. 8:23-30). Barth clearly does not show or describe this missing feature. Further, neither cited reference shows or suggests protrusions extending into or deforming a covering a specified distance with respect to the stent (i.e., “do not reach radially outwardly as far as the luminal envelope” or “without intersecting a plane along the luminal wall surface”), as recited respectively in claims 3 and 10. The threads of the Barth screw can not fairly be characterized as the claimed protrusions for deforming or extending into a covering for a stent as one skilled in the art would clearly recognize, at least because the design of the Barth

screw (e.g., height of the thread, varying heights, etc.) is configured to solve a completely different problem, as discussed above. For instance, the Barth screw is purportedly designed for increased strip torque, versatility for use with materials of varying hardness, etc. Therefore, the Barth screw would not be suitable for deforming or extending into a stent covering as claimed. Accordingly, Applicant submits that there is no disclosure in Barth to lead to the unsupported assertion by the Office Action that “[t]hese protrusions would deform the covering material but would not reach radially outwardly as far as the luminal envelope” (Office Action, p. 6).

In view of the above, Applicant respectfully submits that a *prima facie* case of obviousness is not established by the Office Action because Barth is nonanalogous art and is therefore unsuitable for a rejection of the pending claims under 35 U.S.C. § 103. However, even if Barth is maintained as analogous art, a *prima facie* case of obviousness is not established by the Office Action at least because the asserted combination of Hemerick and Barth does not teach or suggest all of the limitations of claims 3, 10 or 28. Accordingly, Applicant submits that claims 3, 10 and 28 are patentable over the asserted combination and requests favorable reconsideration and withdrawal of the rejection of claims 3-18 and 21-32 under 35 U.S.C. § 103.

Other Asserted Combinations

Dependent claims 4-6, 8, 11-12, 17, 18, 22, 25 and 31 are separately rejected over various combinations of references as detailed above. Without conceding the propriety of these asserted combinations, Applicant submits that each of claims 4-6, 8, 11-12, 17, 18, 22, 25 and 31 depends from a patentable independent claim and is therefore patentable. Accordingly, Applicant requests favorable reconsideration and withdrawal of the rejection of these claims under 35 U.S.C. § 103.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 480052000700. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: December 28, 2007

Respectfully submitted,

Electronic signature: /Todd W. Wight/
Todd W. Wight

Registration No.: 45,218
MORRISON & FOERSTER LLP
19900 MacArthur Boulevard
Irvine, California 92612-2445
(949) 251-7189